

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Michael Carl Junger

Atty. Docket No.: PA-5386-RFB

Customer No.:

Serial No.: 10/816,288

Group Art Unit: 3763

Filed: 04/01/2004

Examiner: Bouchelle, Laura A

Title: Aspiration and Flushing Needle

AFFIDAVIT

I, Dr. John Allan of
declare as follows.

Wesley Hospital, Brisbane

- 1/ I am a reproductive medicine surgeon practicing at the Wesley Reproductive Medicine & Gynaecological Surgery Unit and I have had 23 years experience in the procedures involved in the removal of oocytes for in vitro fertilization (IVF) procedures.
- 2/ I have been supplied with a copy of United States Patent No. 4,634,420 in the name of Spinoso and Spinoso (Spinoso) and a copy of US Patent Application Serial No. 10/816,288 in the name of Junger (Junger). I understand that Junger is under examination in the United States Patent and Trade Mark Office and that Spinoso et al has been cited against it.
- 3/ I have been asked to comment on whether the device depicted by Spinoso is similar to the device disclosed and claimed in Junger and whether the Spinoso device could be used for IVF procedures.
- 4/ From my review of Spinoso I note that the specification discloses a pulverizing device for removal of tissue from a human or animal body and more particularly for the removal of unwanted tissue from the eye by a process described as microchipping. For this process Spinoso describes a device which has a sealed body with a probe connected to an ultrasonic vibrator. The probe is vibrated at an amplitude sufficient to pulverize tissue to be removed so that it can be aspirated as a pulp. In some embodiments the probe has a blunt tip with a side port (Figure 4) or a front port (Figure 5) or a sharpened probe (Figure 1).

5/ I also observe from my review of Spinosa that the device depicted is not intended to be assembled or dismantled by a user. The device has sealing ring on its handle portion which engages into a groove in the probe to provide sealing for aspiration. There is no mechanism depicted to enable a user to achieve separation of the parts.

6/ The process of oocytes removal from a female patient is an extremely delicate operation involving placement of a long needle into an ovary of the patient under ultrasonic guidance. In one aspiration system a double lumen needle is used as illustrated in Junger. Junger discusses the alternative single and double needle systems on page 2.

7/ In the double lumen needle system depicted in Junger, flushing fluid is supplied through the lumen between the inner and outer needles and aspiration is provided through the inner needle.

8/ The process of oocyte extraction involves puncturing a follicle of the ovary of the patient to reveal the oocytes within without damaging the oocytes. Aspiration is used to extract oocytes along with fluid within the follicle. Flushing fluid is then added and aspiration is again used to extract any further oocytes.

9/ The essence of the process of oocyte extraction is that it is a very delicate operation. Oocytes have a gel coating and this should not be damaged in the aspiration process. The device disclosed in Spinosa is not in any way adapted for or constructed in a way which would enable it to be used as a device for aspiration of oocytes. A reproductive medicine surgeon would not be able to use the device of Spinosa for this purpose and would not understand that such a device as being equivalent to that of Junger.

10/ I make this statement because of three main points as discussed below.

11/ The probe of Spinosa is not a needle in the generally understood meaning of the term and could not be used for oocyte extraction.

12/ The ultrasonic vibration facility of Spinosa would be contraindicated for use in IVF treatment as it may terminally damage an oocyte.

13/ There is a significant advantage in being able to disassemble a device before a procedure to ensure it is entirely clean and during a procedure if tissue is caught in one of the lumens. The Junger device includes a connector to enable separation but the Spinosa device

has no such arrangement.

14/ For all of these reasons I think that a reproductive medicine surgeon would not be taught how to construct a double lumen aspiration apparatus for oocytes extraction from Spinoza.

AND I MAKE this Affidavit conscientiously believing same to be true and correct in every particular. All statements made of my own knowledge are true and that all statements made on information and belief are believed to be true.

Signed



Dr. John Allan, M.B.B.S. (QLD), F.R.A.N.Z.C.O.G.

Before me:



Position:

Solicitor

Date:

8th January 2007